NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PURDUE PHARMACEUTICAL PRODUCTS, L.P., et al.

Plaintiffs,

v.

ACTAVIS ELIZABETH, LLC, et al.

Defendants

PURDUE PHARMACEUTICAL PRODUCTS, L.P., et al.

Plaintiff,

v.

TWI PHARMACEUTICALS, INC.

Defendants.

Civil Action No. 12-5311 (JLL)
[Consolidated with Civil Action No. 13-5003]

OPINION

LINARES, District Judge.

This patent infringement action stems from various generic drug manufacturers' attempts to obtain Food and Drug Administration ("FDA") approval to market a generic version of Plaintiffs/Counterclaim Defendants Purdue Pharmaceutical Products, L.P. ("Purdue Pharmaceutical"), Purdue Pharma, L.P. ("Purdue Pharma"), and Transcept Pharmaceuticals, Inc. ("Transcept") (collectively "Plaintiffs")'s Intermezzo®, a drug used to treat middle-of-the-night insomnia.

Plaintiffs have moved to dismiss Defendant/Counterclaim Plaintiff TWI Pharmaceuticals, Inc. ("TWi")'s counterclaims seeking declaratory judgment of non-infringement of two patents covering Intermezzo® pursuant to Federal Rule of Civil Procedure 12(b)(1). TWi has opposed Plaintiffs' motion, and has cross-moved for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c). The Court has considered the submissions made in support of, and in opposition to Plaintiffs and TWi's respective motions,[1] and decides this matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, both Plaintiffs' motion and TWi's cross-motion are denied.

I. BACKGROUND

A. Statutory Framework

In enacting the Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (the "Hatch-Waxman Act"), "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). "Under the Hatch-Waxman framework, a brand-name company seeking FDA approval of a new drug must file a new drug application ("NDA") with the . . . [FDA]." *Dey Pharma, LP v. Sunovision Pharms., Inc.*, 677 F.3d 1158, 1159 (Fed. Cir. 2012). The NDA must include "information regarding the new drug's safety and efficacy obtained from clinical trials." *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355 (Fed. Cir. 2008). The NDA must also include "information

[1] The Court has considered *all* of the parties' submissions in spite of the fact that Plaintiff's brief in opposition to TWi's cross-motion (Docket Entry No. 139) and TWi's reply brief in support of its cross-motion (Docket Entry No. 140) are not in compliance either Magistrate Judge Joseph A. Dickson's scheduling order entered on March 6, 2014 or with the Local Civil Rule 7.1(h). All counsel are reminded that it is critical that they strictly comply with this Court's orders and with the Local Civil and Patent Rules.

about patents 'with respect to which a claim of patent-infringement could reasonably be asserted.'" *Dey*, 677 F.3d at 1159 (quoting 21 U.S.C. § 355(b)(1)). The FDA publishes the patent information in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, a publication that is also known as the "Orange Book." 21 U.S.C. § 355(b)(1); *see also Andrx*, 276 F.3d at 1371. Once the FDA approves a new drug, that drug becomes known as a "listed drug." 21 U.S.C. § 355(j)(2)(A)(i).

"To encourage the development of generic versions of listed drugs, the [Hatch-Waxman] Act created an expedited approval process known as an Abbreviated New Drug Application (ANDA)." *Janssen,* 540 F.3d at 1355-56 (citing 21 U.S.C. § 355(j)). Filing an ANDA obviates the need for generic drug companies to conduct clinical trials to prove the safety and efficacy of generic versions of listed drugs; under the Hatch-Waxman Act, generic drug companies may rely on the research of the NDA filer so long as they demonstrate in the ANDA that its generic product is bioequivalent to the NDA drug. *See* 21 U.S.C. § 355(j)(2)(A), (j)(8)(B). "The ANDA applicant must also include a certification to each patent listed in the Orange Book covering the listed drug that either (I) no patent information has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a particular date and approval of the ANDA should be deferred until expiration; or (IV) in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug." *Janssen*, 540 F.3d at 1356 (citing 21 U.S.C. § 355(j)(2)(A)(vii)).

The time within which the FDA will act on a generic drug company's request for approval depends on the type of certification included in the ANDA. "If [as in this case] an ANDA contains only paragraph IV certifications, the ANDA may be approved unless the NDA filer sues the ANDA filer for patent infringement within 45 days" of receiving notice of the

ANDA filing. *Dey*, 677 F.3d at 1159 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).[2] The first drug company that files an ANDA containing a paragraph IV certification is entitled to a 180-day period of generic marketing exclusivity before the FDA may approve any later paragraph IV ANDA based on the same NDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv)).

Before Congress amended the Hatch-Waxman Act in 2003, the first ANDA filer's 180-day exclusivity period was triggered by either its "first commercial marketing of the [generic] drug," or a judicial decision "holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv) (2000). In 2003, however, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 1102, 117 Stat. 2066, 2457-60, which amended the Hatch-Waxman Act's provisions governing a first ANDA filer's exclusivity period. Under the MMA, only the first ANDA filer's commercial marketing may trigger the 180-day exclusivity period. *See* 21 U.S.C. § 355(j)(5)(B)(iv). But the first ANDA-filer's 180-day exclusivity period can be forfeited under certain circumstances. For instance, if a later ANDA-filer obtains a final judgment that each of the listed drug's Orange Book patents are invalid or not infringed, the first ANDA filer must market its product within 75 days of the later ANDA filer's judgment, or forfeit its period of exclusivity. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I).

B. Factual Background[3]

Purdue Pharmaceutical is the current holder of NDA No. 022328, for sublingual tablets containing 1.75 mg and 3.5 mg of zolpidem tartrate, which the FDA approved on November 23, 2011 to treat middle-of-the-night insomnia. (Purdue's Compl. against TWi (hereinafter,

[2] Under the Hatch-Waxman Act, the filing of an ANDA is an act of infringement. *See* 35 U.S.C. § 271(e)(2).

[3] The Court sets forth only those facts which are specifically relevant to deciding the pending motions.

"Compl.") at ¶ 16.) Purdue Pharma markets the approved drug under the tradename Intermezzo®. (*Id.*)

There are four patents covering Intermezzo® which are listed in the Orange Book: (1) U.S. Patent No. 7,658,945 (the "'945 Patent") entitled "Compositions for delivering hypnotic agents across the oral mucosa and methods of use thereof; (2) U.S. Patent No. 7,682,628 (the "'628 Patent") entitled "Compositions for delivering hypnotic agents across the oral mucosa and methods of use thereof; (3) U.S. Patent No. 8,242,131 (the "'131 Patent") entitled "Methods of Treating Middle-of-the-Night Insomnia; and (4) U.S. Patent No. 8,252,809 (the "'809 Patent") entitled "Compositions for Treating Insomnia." (TWi's Counterclaim ("Counterclaim") at ¶¶ 1, 8-13.) Transcept owns these four patents. (Counterclaim at ¶ 13.) Purdue Pharmaceuticals and Purdue Pharma are the exclusive licensees for these patents. (*See* Compl. at ¶ 18.)

On or before July 8, 2013, TWi submitted an ANDA with paragraph IV certifications to the FDA for 1.75 mg and 3.5 mg zolpidem tartrate sublingual tablets, purportedly bioequivalent to Intermezzo®. (Compl. at ¶ 19.) By the time TWi submitted this ANDA to the FDA, at least four other generic drug companies had already submitted ANDAs seeking FDA approval to market generic versions of Intermezzo®. (*See, e.g.,* Plaintiffs' Consolidated Complaint asserting patent infringement claims against various defendants, Civil Action No. 12-5311, Docket Entry No. 36.)

On August 20, 2013, Plaintiffs filed a two-count complaint seeking a declaratory judgment that TWi has: (1) infringed the '131 Patent, and (2) infringed the '809 Patent. (Civil Action No. 13-5003, Docket Entry No. 1.) Notably, Plaintiffs did not assert any claims involving the '945 or '628 patents against TWi. On October 17, 2013, TWi filed a Counterclaim seeking declaratory judgment that all four patents listed in the Orange Book listing for Intermezzo® are not infringed. (*See* Counterclaim at ¶¶ 19-36.)

On January 24, 2014, Plaintiffs tendered a covenant "not to sue TWi under any patent claim of" either the '945 or the '628 patents in connection with TWi's ANDA seeking approval to manufacture, use and sell a generic version of Intermezzo®. (*See* Civil Action No. 12-5311, Docket Entry No. 117-1.) Plaintiffs' covenant does not contain any language suggesting either that the '945 and '628 patents are invalid, or that TWi has not infringed these patents. In fact, the covenant specifically states that it "does not . . . constitute an admission by any Plaintiff as to the scope or interpretation of, the infringement of, the validity of, or the enforceability of, *any* patent (including but not limited to [the '945 and '628 patents])." (*Id.*) (emphasis added).

II. LEGAL STANDARD

A. Motion to Dismiss for Lack of Subject Matter Jurisdiction

It has long been a well settled "'fundamental precept that federal courts are courts of limited jurisdiction,' empowered to act only within the bounds of Article III of the United States Constitution." *Highway Equip. Co. v. FECO, Ltd.*, 469 F.3d 1027, 1032 (Fed. Cir. 2006) (quoting *Owen Equip. & Erection Co. v. Kroger*, 437 U.S. 365, 374 (1978)). Under Article III of the United States Constitution, federal courts may adjudicate only cases or controversies. U.S. Const. Art. III.

The Declaratory Judgment Act provides that, "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). As the Federal Circuit has recognized, "the Declaratory Judgment Act does not provide an independent basis of subject matter jurisdiction." *Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1327-28 (Fed. Cir. 2012). Rather, "[i]ts remedy may lie only if the court has jurisdiction from some other source." *Cat Tech, LLC v. TubeMaster, Inc.*, 528 F.3d 871, 879 (Fed. Cir. 2008). "The party seeking to

establish declaratory jurisdiction bears the burden of demonstrating that an Article III case or controversy exists at the time the claim for declaratory relief is filed." *Matthews*, 695 F.3d at 1328.

"In the Hatch-Waxman context, Congress extended declaratory judgment jurisdiction to ANDA paragraph IV disputes, 21 U.S.C. § 355(j)(5)(C), and has directed federal courts to exercise jurisdiction over these disputes 'to the extent consistent with the Constitution,' 35 U.S.C. § 271(e)(5)." *Dey*, 677 F.3d at 1162. Federal courts are empowered to exercise declaratory judgment jurisdiction when "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)). In other words, a declaratory judgment action is "justiciable under Article III only where (1) the plaintiff has standing, (2) the issues presented are ripe for judicial review, and (3) the case is not rendered moot at any stage of the litigation." *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008) (internal citations omitted).

B. Motion for Judgment on the Pleadings

Federal Rule of Civil Procedure 12(c) provides that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Under Rule 12(c), a court must view the facts in the pleadings and any inferences drawn therefrom in the light most favorable to the nonmoving party. *Sikirica v. Nationwide Ins. Co.*, 416 F.3d 214, 220 (3d Cir. 2005). "Judgment will not be granted unless the movant clearly establishes there are no material issues of fact, and he is entitled to judgment as a matter of law." *Id.*

III. DISCUSSION

A. Plaintiffs' Motion to Dismiss

Plaintiffs have moved to dismiss TWi's counterclaims relating to the two patents for which they have given a covenant not to sue (*i.e.*, the '945 and '628 patents). In support of their motion to dismiss, Plaintiffs make three arguments: (1) "[n]o Article III case or controversy exists" over the counterclaims relating to the '945 or '628 patents because the "covenant not to sue rendered moot any such controversy," (Pl. Br. at 4); (2) "[n]o Article III case or controversy exists under the Hatch-Waxman Act because the Court cannot redress TWi's alleged injury," (Pl. Br. at 4); and (3) "[n]o Article III case or controversy exists because the dispute is not ripe in light of TWi's inability to obtain tentative approval [from the FDA]," (Pl. Br. at 4-7). For the reasons that follow, Plaintiffs' arguments do not persuade the Court that it would be appropriate to dismiss TWi's counterclaims relating to the '945 and '628 patents.

1. Plaintiffs' Covenant not to Sue does not Render Moot TWi's Counterclaims relating to the '945 Patent and the '628 Patent

"The mootness doctrine requires that the requisite personal stake that is required for a party to have standing at the outset of an action must continue to exist throughout all stages of the action." *Caraco*, 527 F.3d at 1296. "[A] case is moot when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome" *Powell v. McCormack*, 395 U.S. 486, 496 (1969). In declaratory judgment actions, "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of declaratory judgment." *MedImmune*, 549 U.S. at 771.

Plaintiffs maintain that because their "covenant eliminated all risk that TWi would face infringement liability for its ANDA product under the '945 and '628 patents," there is no justiciable case or controversy for this Court to resolve. (Pl. Br. at 4.) Plaintiffs' argument is premised on the assumption that without the actual threat of an infringement lawsuit concerning

the '945 and '628 patents, TWi has no cognizable legal interest in seeking judicial review of whether it has infringed these patents. But this argument fails to account for the reality that as a later ANDA filer, the FDA cannot approve TWi's ANDA to market a generic version of Intermezzo® until the first filer's 180-day exclusivity period is either forfeited or runs out. And one of the ways that TWi may trigger the first ANDA filer's exclusivity period so as to precipitate its own entry into market is by obtaining a final favorable judgment on all Orange Book listed patents for Intermezzo®, including the '945 and '628 patents. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I).

There is ample authority supporting the proposition that a later ANDA filer's declaratory judgment claims involving patents for which the patent holder has given a covenant not to sue are justiciable. *Dey*, for example, involved a second ANDA filer's declaratory judgment action against a patent holder designed to trigger the first ANDA filer's exclusivity period. 677 F.3d at 1161. The patent holder had sued the second ANDA filer for infringement of two out of three patents listed in the Orange Book for the drug at issue. *Id.* The second ANDA filer then brought a declaratory judgment action seeking a declaration that the third patent was either invalid or not infringed. *Id.* In response, the patent holder provided a covenant not to sue on the third patent, and filed a motion to dismiss the second ANDA filer's declaratory judgment claim for lack of subject matter jurisdiction. *Id.*

The Federal Circuit affirmed the district court's denial of the patent holder's motion to dismiss, rejecting the notion that the covenant not to sue mooted the second ANDA filer's declaratory judgment action. *Id.* at 1164. The Federal Circuit also held that the second ANDA filer's claim was justiciable because a favorable judgment on this claim would "eliminate the *potential* to exclude [the second ANDA filer] from the market," as such a judgment could serve to trigger the first ANDA filer's exclusivity period so long as the later ANDA filer also obtained a

favorable judgment on the other two patents at issue in the action brought by the patent holder. *See id.* at 1164 (emphasis added). Specifically, the court held that "eliminating one barrier [to market entry] is sufficient for declaratory jurisdiction, so long as litigation is also pending that could eliminate the other barriers."[4] *Id.*

Similarly, in *Caraco* the Federal Circuit rejected the argument that declaratory judgment actions concerning patents over which the patent holder has granted a covenant not to sue categorically are non-justiciable. *Caraco* involved an NDA filer which sued a second ANDA filer for infringement of one of two patents listed in the Orange Book for the drug at issue. 527 F.3d at 1288. The second ANDA filer then brought a declaratory judgment action over the patent on which the NDA filer decided not to sue. *Id.* In response, the NDA filer gave the second ANDA filer a covenant not to sue covering the patent that was the subject of the second ANDA filer's declaratory judgment action. *Id.* at 1289. The Federal Circuit held that the second ANDA filer's action was justiciable in spite of the covenant not to sue because the NDA filer's failure to seek judicial resolution of one of the Orange Book patents could "potentially exclude non-infringing generic drugs from the market" by foreclosing the second ANDA filer's ability to trigger the first ANDA filer's exclusivity period. *See id.* at 1292. The court also held that the second ANDA filer's declaratory judgment action was not mooted by the NDA filer's covenant not to sue because resolution of "the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents" could potentially trigger the first ANDA filer's exclusivity period, and said dispute thus constituted "'a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of declaratory judgment.'" *See id.* (quoting *MedImmune*, 549 U.S. at 127).

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[4] In *Dey*, there was litigation pending that "could eliminate the other barriers," as all three patents listed in the Orange Book were the subject of litigation. *See generally* 677 F.3d 1158.

Indeed, the binding principles the Federal Circuit set forth in *Dey* and *Caraco* compel this Court to conclude that Plaintiffs' covenant not to sue TWi on the '945 and '628 patents does not moot TWi's counterclaims seeking declaratory judgment that these patents are not infringed. Like the later ANDA filers' claims in *Dey* and *Caraco*, TWi's counterclaims could potentially trigger the first ANDA filer's 180-day exclusivity period. This would have the effect of expediting TWi's ability to market its generic version of Intermezzo®. Accordingly, this Court holds that TWi's counterclaims present a substantial controversy appropriate for judicial review.

2. TWi's Injury is Sufficiently Redressable

TWi must establish that it has standing to pursue its counterclaims concerning the '945 and '628 patents for these counterclaims to be justiciable. The "irreducible constitutional minimum of standing contains three requirements:" (1) a concrete injury that is (2) "fairly traceable" to the complained of conduct which is (3) likely to be redressed should the court grant the requested relief. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102-03 (1998). According to Plaintiffs, TWi fails to satisfy the third of the standing requirements. Specifically, Plaintiffs argue that a judgment favorable to TWi on the '945 and '628 patents will not redress any injury arising from delay in TWi's ability to market its generic version of Intermezzo® because such a judgment would not independently trigger the first ANDA filer's exclusivity period as TWi has not received tentative approval from the FDA to market its generic product. (*See* Pl. Br. at 4-5; Pl. Reply Br. at 2-3.)

In relevant part, the Hatch-Waxman Act provides that a first ANDA filer will forfeit its 180-day exclusivity period if it fails to market its generic within 75 days from which "any other applicant (which other applicant has received tentative approval)" obtains a "final judgment . . . that each of the patents with respect to which the first [ANDA] applicant submitted and lawfully

maintained a certification qualifying the first applicant for the 180-day exclusivity period . . . is invalid or not infringed." 21 U.S.C. § 355(j)(5)(D)(i)(I)(AA)-(BB). Plaintiffs maintain that because "an applicant in TWi's position cannot trigger the first applicant's exclusivity period through a declaratory judgment action unless it has first received tentative approval," this Court cannot redress TWi's purported injury. (Pl. Reply Br. at 2.) The Court is not persuaded.

Although TWi requires tentative approval from the FDA before it can trigger the first ANDA filer's 180-day exclusivity period, the statute does not explicitly require TWi to obtain tentative approval *before* seeking declaratory judgment of non-infringement with respect to *any* of the Orange Book patents for Intermezzo®. 21 U.S.C. § 355(j)(5)(D)(i)(I). More importantly, to require TWi to obtain tentative approval as a condition precedent to asserting jurisdiction over its counterclaims would undermine the Hatch-Waxman Act's policy of encouraging "early resolution of patent disputes." *See Caraco*, 527 F.3d at 1285. Although the *Caraco* court interpreted a version of the Hatch-Waxman Act that predates the MMA amendments, its observations regarding the general policy underlying the Hatch-Waxman Act are squarely applicable to this case. *See, e.g.*, *Seattle Children's Hospital v. Akorn, Inc.*, No. 10-5118, 2011 U.S. Dist. LEXIS 145998, at *21 (N.D. Ill. Dec. 20, 2011) (observing that "*Caraco* specifically addressed the concept that a generic applicant be permitted to seek prompt resolution of . . . patent issues under the original and amended versions of the [Hatch-Waxman] Act."). The *Caraco* court noted that "Congress explained the need for broad federal jurisdiction over [civil actions to obtain patent certainty] as follows:

> [W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the 'failure to market' provision and force the first generic to market.

> In . . . these . . . circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45-day period. We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes. The declaratory judgment provisions of this bill are intended to encourage such early resolution of patent disputes.

Caraco, 527 F.3d at 1285 (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003)).

Congress's intent in encouraging early resolution of a later ANDA filer's declaratory judgment claims is also reflected in a letter from the Federal Trade Commission that, in relevant part, reads:

> . . . Without the right to seek declaratory judgment, a subsequent generic applicant that develops a clearly non-infringing product cannot trigger the first generic applicant's exclusivity because the subsequent generic applicant will not be sued for patent infringement by the brand-name company. If the brand-name company and the first generic applicant agree that the generic will not begin commercial marketing, then the 180-day exclusivity becomes an absolute bar to any general entrant. Moreover, speedier resolution of patent infringement suits will redound to the benefit of consumers by resolving any possible uncertainty that prevents a generic applicant from marketing its products. *It also will allow for the simultaneous running of the periods for FDA approval and for the resolutions of patent infringement issues.*

149 Cong. Rec. S15886.

Indeed, at least one other district court has rejected the argument that a later ANDA filer must obtain tentative approval from the FDA before declaratory judgment claims regarding patents over which the patent holder has granted a covenant not to sue are justiciable. *See Akorn, Inc.*, 2011 U.S. Dist. LEXIS 145998, at *25. In *Akorn*, an NDA filer moved to dismiss its infringement action against a later ANDA filer for lack of subject matter jurisdiction. *Id.* at *8. Specifically, the NDA filer argued that because it gave the later ANDA filer a covenant not to sue with respect to the patent at issue, its claim was no longer justiciable. *Id.* at *8. In response, the later ANDA

filer maintained that without a final judgment of non-infringement in its favor, it would not be able "to bring about the exhaustion or forfeiture" of the first ANDA filer's 180-day exclusivity period. *Id.* at *13.

Among other things, the NDA filer in *Akorn* argued that any injury arising from the later ANDA filer's inability to trigger the first ANDA filer's exclusivity period could not be redressed by a favorable judgment because the later ANDA filer had "yet to receive 'tentative approval' of its ANDA and there [was] no telling if or when the FDA may approve [the later ANDA filer's] ANDA." *Id.* at *25. Judge Robert M. Dow, of the Northern District of Illinois, rejected this argument on the basis that the "2003 amendments [to the Hatch-Waxman Act] created a civil action to obtain patent certainty ("CAPC") that could be brought by an ANDA applicant at a time when it likely would not have tentative approval." *Id.* Judge Dow reasoned that if the NDA filer had not sued within 45 days of receiving notice of the ANDA filing, the later ANDA filer could have filed a declaratory judgment action against the NDA filer even if it "had not received tentative approval for its ANDA . . . and even if [the NDA filer] had not threatened suit." *Id.* at *27 (citing 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 271(e)(5)). Accordingly, Judge Dow held that "[n]otwithstanding [the NDA filer's] unilateral covenant not to sue, the case or controversy between the parties . . . endures because of the continued listing of [the patent at issue] in the Orange Book . . . which bears on [the later ANDA filer's] efforts to obtain FDA approval to market a generic version of [its drug]." *Id.* at *28.

As far as this Court is aware, the Federal Circuit has not specifically addressed whether a later ANDA filer must have tentative approval prior to bringing a declaratory judgment claim concerning patents over which an NDA filer or patent holder has granted a covenant not to sue. The Court is, nevertheless, mindful that in *Caraco* the Federal Circuit held that "even after a

covenant not to sue has been granted, the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents" is justiciable when a judgment in favor of a later ANDA filer may trigger the first ANDA filer's 180-day exclusivity period. A faithful application of this principle, and of Judge Dow's persuasive reasoning in *Akorn*, compels this Court to hold that TWi has standing to pursue its counterclaims, particularly in light of the Hatch-Waxman Act's policy favoring early resolution of patent disputes.

3. TWi's Counterclaims are Ripe for Judicial Review

"Whether an action is 'ripe' requires an evaluation of 'both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Caraco*, 527 F.3d at 1294-95. "[A]n action is fit for judicial review where further factual development would not 'significantly advance [a court's] ability to deal with the legal issues presented.'" *Id.* (quoting *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803. 812 (2003)). "[W]ithholding court consideration of an action causes hardship to the plaintiff where the complained-of conduct has an 'immediate and substantial impact' on the plaintiff." *Id.* (quoting *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167, 171 (1967)).

Here, TWi's counterclaims satisfy the ripeness requirements. Because TWi "has a complete generic drug product that has been submitted to the FDA for approval," additional factual development would not help this Court determine whether TWi's generic drug "infringes the claims of" Plaintiffs' '945 and '628 patents. *See Caraco*, 527 F.3d at 1295 (holding that later ANDA filer's claims satisfied the fitness prong of the ripeness test because the later ANDA filer's "generic drug product . . . [had] been submitted to the FDA for approval, and no additional facts [were] required to determine whether this drug infringe[d] the claims of" the NDA filer's patent). Moreover, as discussed above, delaying judicial consideration of TWi's counterclaims could result

in depriving TWi of the ability to trigger the first ANDA filer's 180-day exclusivity period, thus causing TWi to lose profits during the period of time it is excluded from the market. *See* 21 U.S.C. § 355(j)(5)(D). Under such circumstances, delay in resolving TWi's counterclaims will have an immediate and substantial impact on TWi. *See Caraco*, 527 F.3d at 1295 (noting that if the later ANDA filer's drug does not infringe on the NDA filer's patent, delay in judicial resolution of later ANDA filer's declaratory judgment action "creates a potential for lost profits" which amounts to "immediate and substantial impact"). Accordingly, this Court holds that TWi's counterclaims are ripe for judicial review.

In light of the Court's conclusion that TWi's counterclaims: (1) are not moot, (2) seek relief that will sufficiently redress an injury so as to confer standing, and (3) are ripe for judicial review, Plaintiffs' motion to dismiss TWi's counterclaims is denied.[5]

B. TWi's Motion for Judgment on the Pleadings

TWi moves for judgment on the pleadings as to its counterclaims on the '628 and '945 patents on the grounds that "there are no disputed facts" and "there is nothing to resolve." (*See* Def. Oppn. Br. at 6.) In their brief in opposition to TWi's cross-motion, Plaintiffs request leave to amend their answer to TWi's counterclaims should this Court hold that TWi's counterclaims are justiciable. (*See* Pl. Oppn. Br. at 4-5.)

Under Federal Rule of Civil Procedure 15(a)(2), courts "should freely give leave [to amend pleadings] when justice so requires." "This approach ensures that a particular claim will be

[5] In the alternative, Plaintiffs argue that this Court should exercise its discretion to decline jurisdiction under the Declaratory Judgment Act. (Pl. Br. at 7.) It is well settled that "even if a case or controversy exists, the trial court has significant discretion in determining whether or not to exercise declaratory judgment jurisdiction." *Matthews*, 695 F.3d at 1328 n.3. "The use of discretion is not plenary, however, for there must be well-founded reasons for declining to entertain a declaratory judgment action." *Elecs for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1345 (Fed. Cir. 2005) (citations and internal quotation marks omitted). As discussed above, declining jurisdiction over TWi's counterclaims would undermine the Hatch-Waxman Act's policy of early resolution of patent disputes. Thus, the Court will not exercise its discretion to decline jurisdiction over TWi's counterclaims concerning the '945 and '628 patents.

decided on the merits rather than on technicalities." *Dole v. Arco Chemical Co.*, 921 F.2d 484, 487 (3d Cir. 1990). "Nonetheless, leave to amend may be denied if the court finds that there has been undue delay that would prejudice the nonmoving party, that the moving party has acted in bad faith, or that the amendment would be futile." *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. De. C.V.*, 464 F.3d 1339, 1353 (Fed. Cir. 2006). Whether to grant any party leave to amend is a decision left to the "sound discretion of the District Court." *E.g., Winer Family Trust v. Queen*, 503 F.3d 319, 331 (3d Cir. 2007).

Here, there is nothing to suggest that Plaintiffs have caused undue delay in seeking leave to amend their answer, or that TWi would be unduly prejudiced by granting Plaintiff's such leave. Accordingly, the Court will exercise its discretion to allow Plaintiffs to amend their answer to TWi's counterclaims. As the Court will allow Plaintiffs to amend their answer, it will deny TWi's cross-motion for judgment on the pleadings as moot. TWi may renew its motion for judgment on the pleadings after Plaintiffs file their amended answer should it believe that it is entitled to such relief.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' motion to dismiss TWi's counterclaims on the '945 and '628 patents is denied, as is TWi's cross-motion for judgment on the pleadings. TWi may file an amended answer to TWi's counterclaims within fourteen days from the date of entry of the Order accompanying this Opinion. Additionally, to the extent they have not already done so, Plaintiffs and TWi must abide by Magistrate Judge Joseph A. Dickson's Order of March 6, 2014 requiring them to "confer and identify any disputed claim terms not already briefed . . . requiring supplemental briefing by Plaintiffs and TWi in advance of the *Markman* hearing scheduled . . . for

May 8, 2014." (*See* Am. Scheduling Order of Mar. 6, 2014 at ¶ 2, Docket Entry No. 132.)[6] Under no circumstances will this Court grant any requests to adjourn the *Markman* hearing scheduled for May 8, 2014.

An appropriate Order follows.

Dated: 9th of April, 2014.

JOSE L. LINARES
U.S. DISTRICT JUDGE

[6] The Court is mindful that TWi has requested that Plaintiffs provide a list of disputed claim terms with respect to the '628 and '945 patents. The Court fails to see how the scheduling order that Judge Dickson entered on March 6, 2014 does not address this request. For the avoidance of confusion, Plaintiff and TWi shall serve on each other a complete list of claim terms which each party contends this Court must construe in advance of the *Markman* hearing scheduled on May 8, 2014, and strictly comply with all deadlines set forth in Judge Dickson's March 6, 2014 Order.